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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/940,722	08/27/2001	Ronald A. Schachar	PRES06-00217	5803

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Docket Clerk  
P.O. Drawer 800889  
Dallas, TX 75380

EXAMINER
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WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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10/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/940,722	SCHACHAR, RONALD A.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Dave Willse	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 June 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 61-115 is/are pending in the application.
- 4a) Of the above claim(s) 71-73, 91-93 and 104-106 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 61-70, 74-90, 94-103, 107-115 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-8-08</u> .  | 6) <input type="checkbox"/> Other: _____                          |

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Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. The limitations pertaining to the pocket “extending generally circumferentially completely around the lens of the eye” (claim 1, lines 3-4) and “any members that are attached to the body” (claim 1, line 7) are not supported in the original disclosure. Because of the procedure for interpreting such claims as set forth in MPEP § 2163.06, prior art may be applicable to any subsequently amended version of claim 1.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 61-70, 80-88, 90, 94-101, 103, and 108-115 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schachar, US 5,354,331. Regarding claim 61 and others, the “scleral alloplant” for replacing “a small strip of sclera” (column 8, lines 22-26) inherently possesses opposite side surfaces and opposite end surfaces for contacting a portion of the sclera when the prosthesis is implanted. The means for expanding the contacted sclera involve the

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weakening of the sclera in a region of the ciliary body (column 8, lines 3-4 and 10-12) in conjunction with internal ocular pressure (column 7, lines 48-53) and the filling of the excision site with the alloplant. Regarding claim 62, the ridge or crest corresponds to an anterior edge of the alloplant, which maintains the spacing of excision site walls. Regarding claim 63, the aforementioned surfaces are *capable* of contacting ocular tissue within a pocket, whether or not such was the intent.

Schachar '331 also discloses an ocular scleral prosthesis in the form of an adjustable scleral expansion band (column 7, lines 1-4) comprising at least one elongated body in the form of a strip of material (column 7, lines 4-8) capable of being implanted in a corresponding elongated pocket within scleral tissue of an eye in the zone exterior to the ciliary body (column 7, lines 36-39). Inner and outer surfaces of said band are capable of contacting the base and the flap of the scleral pocket (column 7, lines 39-42; drawings) and are separated by enough distance or thickness to impart sufficient structural characteristics (e.g., strength) to elevate the flap and exert outwardly directed traction on at least the anterior margin of the pocket (column 7, lines 8-12; column 5, lines 38-41; etc.). Regarding claim 80 and others, because the elongated body is of a partial frustoconical shape, an outer anterior edge defines a ridge projecting above surrounding portions of the body. Regarding claim 94 and others, the scleral expansion band constitutes a *single* prosthesis, so the "body" as claimed may contact or engage other components of the *same* prosthesis and still meet limitations like "spaced apart from any *other* prosthesis" (claim 94, last line; emphasis added).

Claims 61-70, 74-79, 89, 102, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schachar, US 5,354,331. The "plurality" (column 7, line 2) being interpreted

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as three or more would have been obvious to the ordinary practitioner in order to facilitate implantation by reducing the extent to which each strip must be inserted into the sclera. Each strip or body in such a configuration would then have ends that are linearly more distal from one another than from any other portion of the strip or body. Regarding claim 69 and others, the particular dimensions would have been obvious in order to accommodate a range of ocular dimensions found in humans and other animals.

The Applicant's remarks have been considered and are adequately addressed in the grounds of rejection above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, whose telephone number is 571-272-4762 and who is generally available Monday, Tuesday, and Thursday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on

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571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**/Dave Willse/  
Primary Examiner  
Art Unit 3738**